

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

-----X  
NARVEEN DORSANJH,

Plaintiff,

-against-

ZELTIQ AESTHETICS, INC.,

Defendant.  
-----X

**CASE NO:**

**COMPLAINT AND**  
**JURY DEMAND**

Plaintiff, by her attorneys, **DOUGLAS & LONDON, P.C.**, upon information and belief,  
at all times hereinafter mentioned, allege as follows:

**JURISDICTION**

1. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiff is a citizen of a state which is different from the State where Defendant is incorporated and has its principal places of business. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS (\$75,000.00).

**NATURE OF CASE**

2. This is a products liability action that seeks recovery for the severe personal injuries, pain and suffering and other damages sustained by Plaintiff, NARVEEN DOSANJH, as a result of the use of Defendant's CoolSculpting device.

3. Defendant ZELTIQ AESTHETICS, INC. (hereinafter referred to as "Defendant," or "Zeltiq,") created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold its CoolSculpting device to be used on individuals to induce

lipolysis (the breaking down of fat cells) in the body, and said CoolSculpting device was used on Plaintiff NARVEEN DOSANJH.

4. Defendant's CoolSculpting device was defective and, as a result, Plaintiff NARVEEN DOSANJH has suffered and continues to suffer severe and permanent personal injuries, including but not limited to adipose hypertrophy, as well as other severe and permanent health consequences that are lasting in nature.

**PARTY PLAINTIFFS**

5. Plaintiff NARVEEN DOSANJH is and was at all relevant times a resident of the State of New York, County of New York.

6. Plaintiff NARVEEN DOSANJH was born on April 2, 1977.

7. On or about December 19, 2013, Plaintiff NARVEEN DOSANJH underwent a procedure in which Defendant's CoolSculpting Device was used on her left thigh and her right thigh for the purpose of inducing lipolysis – the breaking down of fat cells.

8. As a direct and proximate result of the use of Defendant's CoolSculpting Device on her left and right thighs, Plaintiff NARVEEN DOSANJH suffers from and was diagnosed with adipose hypertrophy and all injuries and damages associated therewith.

9. Plaintiff NARVEEN DOSANJH has had to undergo multiple surgeries and procedures to correct the injuries caused by Defendant's CoolSculpting Device.

10. As a direct and proximate result of her use of Defendant's CoolSculpting Device, Plaintiff NARVEEN DOSANJH has experienced and continues to experience severe pain and suffering, and has sustained permanent injuries and emotional distress.

**PARTY DEFENDANT**

11. Defendant ZELTIQ AESTHETICS, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 4698 Willow Road, Pleasanton, California 94588.

12. Defendant ZELTIQ AESTHETICS, INC. at all times relevant herein was in the business of creating, designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing its CoolSculpting device into the stream of commerce for use by the public, including Plaintiff NARVEEN DOSANJH.

13. Defendant ZELTIQ AESTHETICS, INC. has transacted and conducted business in the State of New York.

14. Defendant ZELTIQ AESTHETICS, INC. has derived substantial revenue from goods and products used in the State of New York.

15. Defendant ZELTIQ AESTHETICS, INC. expected or should have expected its acts to have consequences within the State of New York, and derives substantial revenue from interstate commerce within the United States of America, and the State of New York, more particularly.

**FACTUAL ALLEGATIONS**

11. Defendant, either directly or through its agents, servants, and employees, created, designed, manufactured, marketed, advertised, distributed, and sold its CoolSculpting device to be used on individuals to induce lipolysis (the breaking down of fat cells) in the body.

12. Defendant's CoolSculpting device is a Class II medical device, as defined and categorized by the U.S. Food and Drug Administration ("FDA"), to be used on individuals to, among other things, induce lipolysis in the body.

13. Defendant's CoolSculpting device was first cleared by the FDA pursuant to the 510(k) process on or about May 31, 2006 to be used as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments and as a local anesthetic for procedures that induce minor local discomfort.

14. Within its May 31, 2006 510(k) clearance, the FDA had not cleared Defendant's CoolSculpting device to be used to induce lipolysis.

15. The FDA did not clear Defendant's CoolSculpting device to be used to induce lipolysis until August 24, 2010.

16. Upon information and belief, between May 2006 and August 2010, despite lack of clearance from the FDA, Defendant promoted, advertised and/or marketed to physicians, healthcare providers and the public that its CoolSculpting device be used on individuals to induce lipolysis in certain parts of the body, including the flanks, abdomen and thighs.

17. When the FDA first cleared Defendant's CoolSculpting device to induce lipolysis on August 24, 2010, the FDA's clearance only cleared it to be used on the body's flanks.

18. In May 2012, the FDA expanded its 510(k) clearance regarding Defendant's CoolSculpting device to include inducing lipolysis in the abdomen.

19. Upon information and belief, between August 2010 and May 2012, despite lack of clearance from the FDA, Defendant was promoting, advertising and/or marketing to physicians, healthcare providers and the public that its CoolSculpting device be used on individuals to induce lipolysis in the abdomen.

20. In April 2014, the FDA further expanded its 510(k) clearance regarding Defendant's CoolSculpting device to include inducing lipolysis in the thighs.

21. Upon information and belief, between August 2010 and April 2014, despite lack of clearance from the FDA, Defendant was promoting, advertising and/or marketing to physicians, healthcare providers and the public that its CoolSculpting device be used on individuals to induce lipolysis in the thighs.

22. At all times Defendant were promoting, advertising and/or marketing its CoolSculpting device to physicians and/or healthcare providers, they were representing to these physicians and/or healthcare providers that a CoolSculpting procedure was “not technique dependent.”

23. Upon information and belief, Defendant knew and/or should have known that its CoolSculpting device was associated with post-surgical tissue growth through many scientific avenues, including, but not limited to, clinical trial data and adverse event reports.

24. Upon information and belief, since as early as 2007, Defendant began receiving complaints and/or adverse event reports from individuals and/or their physicians regarding post-surgical tissue growth in the areas of the body treated with Defendant’s CoolSculpting device. In some of these reports, these post-surgical growths were formally diagnosed as hypertrophy and/or hyperplasia.

25. Nevertheless, Defendant failed to appropriately and/or adequately warn physicians, healthcare providers, and the public, including Plaintiff NARVEEN DOSANJH, of the risk of developing post-surgical growths, including but not limited to adipose hypertrophy, when using its CoolSculpting device.

26. Defendant failed to appropriately collect and report post-market surveillance data regarding the number of adverse events reported with its CoolSculpting device.

27. Defendant concealed its knowledge of the unreasonably dangerous risks of its CoolSculpting device from Plaintiff, her physicians, other consumers, and the medical community.

28. As a result of the defective nature of Defendant's CoolSculpting device, those persons who used it, including the Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including but not limited to adipose hypertrophy.

29. On or about December 19, 2013, Plaintiff, NARVEEN DOSANJH, presented to the Laser & Skin Surgery Center of New York, located in New York, New York, and her physician, Dr. Jeremy Brauer, recommended that she undergo a CoolSculpting procedure that would break down the fat cells in both of her thighs.

30. Upon information and belief, Dr. Brauer used Defendant's CoolSculpting procedure on Plaintiff, NARVEEN DOSANJH, in a reasonable and foreseeable manner and pursuant to the instructions for use accompanying the CoolSculpting device.

31. Following her December 19, 2013 CoolSculpting procedure, Plaintiff noticed a growth in both of her thighs where the CoolSculpting device had been used, and that a significant indentation had formed in between the areas of growth on both sides.

32. As a direct and proximate result of her use of Defendant's CoolSculpting device, Plaintiff, NARVEEN DOSANJH, suffers from adipose hypertrophy, including any and all of its sequelae. Plaintiff has had to undergo numerous procedures to attempt to correct the injuries caused by Defendant's CoolSculpting device.

33. As a direct and proximate result of her use of Defendant's CoolSculpting device, Plaintiff, NARVEEN DOSANJH, has experienced and continues to experience severe pain and

suffering, including but not limited to adipose hypertrophy, and has sustained permanent injuries and emotional distress.

**FIRST CAUSE OF ACTION  
AS AGAINST DEFENDANT  
(NEGLIGENCE AND NEGLIGENCE PER SE)**

34. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

35. Defendant had a duty to exercise reasonable care in the creating, designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of its CoolSculpting device into the stream of commerce, including a duty to assure that the products would not cause users to suffer unreasonable, dangerous side effects.

36. Defendant failed to exercise ordinary care in the creating, designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the its CoolSculpting device into interstate commerce in that Defendant knew or should have known that its CoolSculpting device placed users at risk for developing serious and dangerous side effects, including but not limited to adipose hypertrophy and post-surgical growths at the treatment site, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

37. The negligence of Defendant, its agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

- a. manufacturing, producing, promoting, formulating, creating, and/or designing its CoolSculpting device without thoroughly testing it;

- b. manufacturing, producing, promoting, formulating, creating, and/or designing Its CoolSculpting device without adequately testing it;
- c. not conducting sufficient testing programs to determine whether or not its CoolSculpting devices were safe for use, in that Defendant herein knew or should have known that its CoolSculpting devices were unsafe and unfit for use by reason of the dangers to their users;
- d. selling its CoolSculpting devices without making proper and sufficient tests to determine the dangers to their users;
- e. negligently failing to adequately and correctly warn the Plaintiff, the public, and/or the medical and healthcare profession, and/or the FDA of the dangers of its CoolSculpting device;
- f. negligently failing to recall its dangerous and defective CoolSculpting devices at the earliest date that it became known that said its CoolSculpting devices were, in fact, dangerous and defective;
- g. failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, its CoolSculpting devices;
- h. failing to test its CoolSculpting device and/or failing to adequately, sufficiently and properly test its CoolSculpting device;
- i. negligently advertising and recommending the use of the its CoolSculpting devices without sufficient knowledge as to their dangerous propensities;
- j. negligently representing that its CoolSculpting devices were safe for use for their intended purpose, when, in fact, they were unsafe;
- k. negligently designing its CoolSculpting devices in a manner which was dangerous to their users;
- l. negligently manufacturing its CoolSculpting devices in a manner which was dangerous to their users;
- m. negligently producing its CoolSculpting devices in a manner which was dangerous to their users;
- n. negligently assembling its CoolSculpting devices in a manner which was dangerous to their users;



- o. concealing information concerning tests, and/or reports, and/or studies from the Plaintiff showing that its CoolSculpting devices were unsafe, dangerous, and/or non-conforming with accepted industry standards;
- p. improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the public, concerning the severity of risks and dangers of its CoolSculpting device; and
- q. negligently advertising, marketing, and promoting its CoolSculpting device for uses other than those cleared by the FDA, *i.e.*, for inducing lipolysis in the thighs.

38. Defendant violated statutes, rules and ordinances concerning the manufacturing, marketing, and/or testing of their products.

39. Defendant underreported, underestimated and downplayed the serious danger of its CoolSculpting device.

40. Defendant negligently represented the safety risk and/or dangers of the use of its CoolSculpting device.

41. Defendant was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of its CoolSculpting device in that it:

- a. failed to use due care in designing and manufacturing its CoolSculpting device so as to avoid the aforementioned risks to individuals using the CoolSculpting device for its intended purposes;
- b. failed to accompany their products with proper warnings regarding all possible adverse side events associated with the use of its CoolSculpting device;
- c. failed to warn plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;
- d. failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of its CoolSculpting device;
- e. failed to warn Plaintiff, prior to actively encouraging the sale of the its CoolSculpting device, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects; and

f. were otherwise careless and/or negligent.

42. Despite the fact that Defendant knew or should have known that its CoolSculpting device caused unreasonably dangerous side effects, Defendant continued to market, manufacture, distribute and/or sell its CoolSculpting device to consumers, including to the Plaintiff NARVEEN DOSANJH and her healthcare professionals.

43. Based on the aforesaid, Defendant had a duty to warn physicians of the dangers of using its CoolSculpting device but failed to do so.

44. Defendant's actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

45. Defendant knew or should have known that consumers such as the Plaintiff NARVEEN DOSANJH would foreseeably suffer injury, and/or be at increased risk of suffering injury, as a result of Defendant's failure to exercise ordinary care, as set forth above.

46. Defendant's negligence was the proximate cause of Plaintiff NARVEEN DOSANJH's injuries, harm and economic loss which she suffered and/or will continue to suffer.

47. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

48. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health,

incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

49. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SECOND CAUSE OF ACTION  
AS AGAINST DEFENDANT  
(STRICT PRODUCTS LIABILITY)**

50. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

51. At all times herein mentioned, Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed its CoolSculpting devices as hereinabove described that was used by the Plaintiff NARVEEN DOSANJH.

52. That its CoolSculpting devices were expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by Defendant.

53. At those times, its CoolSculpting device was in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, Plaintiff NARVEEN DOSANJH.

54. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the

foreseeable risks exceeded the benefits associated with the design or formulation of the aforesaid CoolSculpting device.

55. At all times herein mentioned, Defendant's CoolSculpting device were in a defective condition and unsafe, and Defendant knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by the Defendant.

56. Defendant knew, or should have known, that at all times herein mentioned, its CoolSculpting devices were in a defective condition, and were inherently dangerous and unsafe.

57. At the time of the Plaintiff's use of its CoolSculpting device, the aforesaid products were being used for the purposes and in a manner normally intended.

58. Defendant with this knowledge voluntarily designed their CoolSculpting devices in a dangerous condition for use by the public, and in particular Plaintiff NARVEEN DOSANJH.

59. Defendant had a duty to create products that were not unreasonably dangerous for their normal, intended use.

60. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were manufactured defectively in that said products left the hands of Defendant in a defective condition and were unreasonably dangerous to their intended users.

61. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant reached their intended users in the same defective and unreasonably dangerous condition in which the Defendant's products were manufactured.

62. Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff NARVEEN DOSANJH, in particular, and Defendant is therefore strictly liable for the injuries sustained by the Plaintiff.

63. Plaintiff NARVEEN DOSANJH could not, by the exercise of reasonable care, have discovered the defective nature of using the CoolSculpting devices herein mentioned and perceived their dangers.

64. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were defective due to inadequate warnings or instructions as Defendant knew or should have known that the products created a risk of serious and dangerous side effects including but not limited to adipose hypertrophy and/or other severe and permanent health consequences.

65. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were defective due to inadequate warnings and/or inadequate testing.

66. The CoolSculpting devices created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects including but not limited to adipose hypertrophy, and/or other severe and permanent health consequences of its CoolSculpting devices, it continued to improperly advertise, market and/or promote its CoolSculpting devices.

67. By reason of the foregoing, Defendant have become strictly liable in tort to Plaintiff NARVEEN DOSANJH for the manufacturing, marketing, promoting, distribution, and selling of the defective products, its CoolSculpting devices.

68. Defendant's defective design, manufacturing defect, and inadequate warnings of its CoolSculpting devices were acts that amounted to willful, wanton, and/or reckless conduct by Defendant.

69. Said defects in Defendant's CoolSculpting devices were a substantial factor in causing Plaintiff's injuries.

70. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

71. As a result of the foregoing, Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

72. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**THIRD CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(BREACH OF EXPRESS WARRANTY)**

73. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

74. Defendant expressly warranted that its CoolSculpting devices were safe and well accepted by users.

75. Defendant's CoolSculpting devices do not conform to these express representations because they are not safe and have numerous serious side effects, many of which were not accurately nor adequately warned about by Defendant.

76. As a direct and proximate result of the breach of said warranties, Plaintiff NARVEEN DOSANJH suffered and/or will continue to suffer, and/or is at increased risk to suffer severe and permanent personal injuries, harm and/or economic loss.

77. Plaintiff did rely on the express warranties of Defendant herein.

78. Members of the medical community, including physicians and/or other healthcare professionals, relied upon the representations and warranties of Defendant in recommending the use of Defendant's CoolSculpting device.

79. Defendant herein breached the aforesaid express warranties, as its CoolSculpting device were defective.

80. Defendant expressly represented to Plaintiff NARVEEN DOSANJH, and/or her physicians, healthcare providers and/or the FDA that its CoolSculpting devices were safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not

produce any dangerous side effects, that the side effects they did produce were accurately reflected in their warnings and that they were adequately tested and fit for their intended use.

81. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that its CoolSculpting devices were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendant.

82. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

83. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

84. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).



**FOURTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(BREACH OF IMPLIED WARRANTIES)**

85. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

86. At all times herein mentioned, Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold its CoolSculpting devices to induce lipolysis.

87. At the time Defendant marketed, sold, and distributed its CoolSculpting device for use by Plaintiff NARVEEN DOSANJH, Defendant knew of the use for which its CoolSculpting device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

88. Defendant impliedly represented and warranted to the users of its CoolSculpting devices and/or their physicians, and/or healthcare providers, and/or the FDA that its CoolSculpting devices were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

89. That said representations and warranties aforementioned were false, misleading, and inaccurate in that its CoolSculpting devices were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

90. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranties of merchantability and fitness for a particular use and purpose.

91. Plaintiff NARVEEN DOSANJH and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether its CoolSculpting devices were of merchantable quality and safe and fit for its intended use.

92. Defendant's CoolSculpting devices were injected into the stream of commerce by Defendant in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

93. Defendant herein breached the aforesaid implied warranties, as its CoolSculpting devices were neither merchantable nor fit for their intended purposes and uses.

94. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

95. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

96. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**FIFTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(FRAUDULENT MISREPRESENTATION)**

97. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

98. Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff and/or the public in general, and or the FDA that its CoolSculpting devices had been tested and were found to be safe and/or effective for inducing lipolysis.

99. These representations made by Defendant were, in fact, false.

100. When said representations were made by Defendant, they knew those representations to be false, and they willfully, wantonly and recklessly disregarded whether the representations were true.

101. These representations were made by said Defendant with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, purchase and/or use its CoolSculpting device to induce lipolysis, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff.

102. At the time the aforesaid representations were made by the Defendant and, at the time the Plaintiff used its CoolSculpting device, Plaintiff NARVEEN DOSANJH was unaware of the falsity of said representations and reasonably believed them to be true.

103. In reliance upon said representations, Plaintiff was induced to and did use Defendant's CoolSculpting device, thereby sustaining severe and permanent personal injuries, and/or being at an increased risk of sustaining severe and permanent personal injuries in the future.

104. Defendant knew and were aware or should have been aware that its CoolSculpting devices had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

105. Defendant knew or should have known that its CoolSculpting devices had a potential to, could, and would cause severe and grievous injury to the users of said product, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

106. Defendant brought its CoolSculpting device to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff NARVEEN DOSANJH.

107. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

108. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that

Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

109. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SIXTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(FRAUDULENT CONCEALMENT)**

110. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

111. At all times during the course of dealing between Defendant and Plaintiff NARVEEN DOSANJH and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the safety of the its CoolSculpting devices for their intended use.

112. At all times during the course of dealing between Defendant and Plaintiff NARVEEN DOSANJH, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the dangers associated with its CoolSculpting device.

113. Defendant knew or were reckless in not knowing that their representations were false.

114. In representations to Plaintiff NARVEEN DOSANJH and/or Plaintiff's healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

- a. That its CoolSculpting device products were not safe;
- b. That the risks of adverse events with its CoolSculpting device were high;

- c. That the risks of adverse events with its CoolSculpting device were not adequately tested and/or known by Defendant;
- d. That Defendant was aware of the dangers of its CoolSculpting device;
- e. Plaintiff was put at risk of experiencing serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish;
- f. That its CoolSculpting devices were manufactured, marketed, produced, and distributed negligently;
- g. That its CoolSculpting devices were manufactured, marketed, produced, and distributed defectively;
- h. That its CoolSculpting devices were manufactured, marketed, produced, and distributed improperly;
- i. That its CoolSculpting devices were designed negligently;
- j. That its CoolSculpting devices were designed defectively; and
- k. That its CoolSculpting devices were designed improperly.

115. Defendant was under a duty to disclose to Plaintiff and/or her physicians, hospitals, and/or healthcare providers, and/or the FDA, the defective nature of its CoolSculpting devices.

116. Defendant had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used them, including the Plaintiff in particular.

117. Defendant's concealment and omissions of material facts concerning, inter alia, the dangers associated with the use of its CoolSculpting devices were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff NARVEEN DOSANJH and/or her physicians, hospitals and/or healthcare providers into reliance and use of its CoolSculpting devices, and to cause them to purchase, recommend, and/or use its CoolSculpting devices.

118. Defendant knew that Plaintiff NARVEEN DOSANJH and/or her physicians, hospitals, and/or healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding its CoolSculpting devices, as set forth herein.

119. Plaintiff NARVEEN DOSANJH, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

120. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

121. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. By reason of the foregoing, Plaintiffs have been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**SEVENTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(NEGLIGENT MISREPRESENTATION)**

123. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. Defendant represented to the medical and healthcare community, and to the Plaintiff NARVEEN DOSANJH, and/or the FDA, and/or the public in general that its CoolSculpting devices had been tested and found to be safe and effective for their intended use.

125. These representations regarding the safety and testing of its CoolSculpting device made by Defendant were, in fact, false.

126. Defendant failed to exercise ordinary care in the representation of its CoolSculpting device, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce, in that Defendant negligently misrepresented the products' high risk of unreasonable, dangerous side effects.

127. Defendant breached their duty by misrepresenting the serious side effects of Its CoolSculpting device to the medical and healthcare community, the Plaintiff NARVEEN DOSANJH and/or the FDA and/or the public in general.

128. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.



129. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

130. By reason of the foregoing, Plaintiffs have been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**EIGHTH CAUSE OF ACTION  
AS AGAINST ALL DEFENDANT  
(FRAUD AND DECEIT)**

132. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. Defendant conducted research and used its CoolSculpting device as part of its research.

134. As a result of Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff NARVEEN DOSANJH, her doctors, hospitals, and/or healthcare professionals, and/or the FDA that its CoolSculpting devices were safe for their intended use.

135. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, the FDA and/or healthcare professionals, including the Plaintiff.

136. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff NARVEEN DOSANJH, as well as her healthcare providers and/or the FDA.

137. The information distributed to the public, the FDA, and the Plaintiff NARVEEN DOSANJH by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

138. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that its CoolSculpting devices were safe for their intended use.

139. The information distributed to the public, the FDA, and Plaintiff NARVEEN DOSANJH by Defendant intentionally included representations that its CoolSculpting devices carried the same risks, hazards, and/or dangers as other available products.

140. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included false representations that its CoolSculpting devices were not injurious to the health and/or safety of its intended users.

141. These representations were all false and misleading.

142. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that its CoolSculpting devices were not as safe as other available anticonvulsant products.

143. Defendant intentionally made material representations to the FDA and/or the public, including the medical profession and the Plaintiff, regarding the safety of its

CoolSculpting devices, specifically but not limited to its CoolSculpting devices not having dangerous and serious health and/or safety concerns.

144. Defendant intentionally made material representations to the FDA and/or the public in general, including the medical profession, and the Plaintiff NARVEEN DOSANJH regarding the safety of its CoolSculpting devices.

145. That it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA, and/or the plaintiff NARVEEN DOSANJH to gain the confidence of the public, the FDA, healthcare professionals, and/or the Plaintiff to falsely ensure the quality and fitness for use of its CoolSculpting devices and induce the public, and/or the Plaintiff to purchase, request, dispense, recommend, implant and/or continue to use said products.

146. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, the FDA, healthcare professionals, and/or Plaintiff that its CoolSculpting devices were fit and safe for use to induce lipolysis.

147. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, the FDA, healthcare professionals, and/or the Plaintiff that its CoolSculpting device was fit and safe for use and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other available products.

148. That Defendant made claims and representations in its documents submitted to the FDA, the public, to healthcare professionals, and the Plaintiff that its CoolSculpting device did not present serious health and/or safety risks.

149. That Defendant made claims and representations in its documents submitted to the FDA, the public, to healthcare professionals, and the Plaintiff NARVEEN DOSANJH that its

CoolSculpting devices do not present health and/or safety risks greater than other available products.

150. That these representations were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

151. That these representations and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff NARVEEN DOSANJH, and/or her healthcare professionals and were made in order to induce the Plaintiff and/or her healthcare professionals to rely upon misrepresentations and caused the Plaintiff and/or her healthcare professionals to purchase, use, rely on, request, dispense, and/or recommend its CoolSculpting device.

152. That Defendant recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of its CoolSculpting device to the public at large, including the Plaintiff, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives.

153. That Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of its CoolSculpting devices by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of its CoolSculpting device.

154. That Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her healthcare professionals, into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on its CoolSculpting

devices and/or that her healthcare providers would dispense, implant, and/or recommend the same.

155. Defendant, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her healthcare professionals, would rely upon the information being disseminated.

156. Defendant utilized direct to consumer advertising to market, promote, and/or advertise its CoolSculpting device.

157. That the Plaintiff and/or her healthcare professionals did in fact rely on and believe the Defendant's representations to be true at the time they were made and relied upon the representations as well as the superior knowledge and was thereby induced to purchase, use and rely on its CoolSculpting devices.

158. That at the time the representations were made, the Plaintiff and/or her healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of its CoolSculpting devices.

159. That the Plaintiff did not discover the dangerous and serious health and/or safety concerns and the false representations of Defendant nor could the Plaintiff, with reasonable diligence, have discovered the true facts.

160. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of its CoolSculpting devices, Plaintiff would not have purchased, used and/or relied on its CoolSculpting device.

161. That the Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff

162. By reason of the foregoing Plaintiff NARVEEN DOSANJH has experienced and continues to experience, serious and dangerous side effects including but not limited to, adipose hypertrophy, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

163. As a result of the foregoing acts and omissions Plaintiff NARVEEN DOSANJH requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and service.

164. By reason of the foregoing, Plaintiffs have been damaged as against the Defendant in the sum of TEN MILLION DOLLARS (\$10,000,000.00).

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiff demands judgment against the Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

4. Awarding Plaintiff reasonable attorney's fees;
5. Awarding Plaintiff the costs of these proceedings; and
6. Such other and further relief as this Court deems just and proper.

Dated: New York, New York  
April 28, 2016

**DOUGLAS & LONDON, P.C.**

By:

  
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**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury as to all issues

  
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MICHAEL A. LONDON (ML-7510)